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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/648,001

08/26/2003

Casey K. Lee

SPINE 3.0-429

3316

530 7590 09/03/2008
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EXAMINER

SHAFFER, RICHARD R

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

09/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/648,001	Applicant(s) LEE, CASEY K.	
	Examiner Richard Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,31-36 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,31-36 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 9th, 2008 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 31-36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al (US Patent Application Publication 2002/0016633) in view of Kalas et al (US Patent 6,379,385).

Lin et al disclose making (**Page 2, Paragraphs 0032 and 0033**) an intervertebral spacer (**Figures 1, 6 and 7**) from bone harvested from the calcaneus with various configurations such as square, rectangular, angled, circular, hexagonal, and a trailing end having angled walls (**22**). Lin et al specifically discuss making horizontal cuts across the metaphysics of a long bone such that anatomical loading for the spacer is the same as the donor location. This would result in cross sections with a thin cortical calcaneus

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bone and a core of cancellous calcaneus bone. The bone as long as it is healthy (as it should be, otherwise it would not be selected as donor bone) would be able to support 1000 pounds due to using the same source of dense cancellous bone from the calcaneus as applicant.

As shown in **Figure 1C**, in order to achieve the final cancellous bone portion (**10/410/510**), additional cuts are required from the original horizontal cuts which ultimately provide for the implants of **Figures 1, 6 and 7**. Therefore, Lin et al disclose cutting a portion of the calcaneus into two or more subsections (each cross-sectional piece).

Lin et al further disclose (**Page 3, Paragraph 0044**) that the implants (**Figures 1, 6 and 7**) could be placed within the lumbar spine.

Lin et al fail to disclose how a cut would specifically be made in the calcaneus from a donor and therefore is silent whether the cut is perpendicular to the long axis of the calcaneus. Lin et al further fail to disclose the implants (**Figures 1, 6 and 7**) having a thin layer of cortical bone surrounding the cancellous bone, with the cancellous bone being at least either 60%, 80%, 95% and/or 98% of the volume of the implant.

Applicant has not stated any unexpected result or benefit of performing cross-sectional cuts perpendicular to the long axis of the calcaneus and actually states that such is not the only possible direction for cutting. It would have been obvious to one having ordinary skill in the art to consider making cross-sectional cuts either perpendicular to the long axis of the calcaneus or perpendicular to the axial loading axis as a matter of mere preference with no unforeseen benefits or results.

It would have been further been obvious to extract the calcaneal bone from a donor of similar genetic composition in cases where the subjects own bone would be detrimental (severe arthritis, cancer, osteoporosis, general bone disease) while reducing the likelihood of tissue rejection by the subject's immune system as well as reducing additional trauma to the patient if bone was acquired from a deceased individual.

Kalas et al teach (**Figures 1 and 2**) spinal implant designs using cortical bone inserts (**12, 22**) with **Figure 1** substantially similar to **Figure 7** of Lin et al. One of ordinary skill in the art would have found it obvious to substitute the cortical bone plug design of **Figure 2** of Kalas et al for that of **Figure 7** of Lin et al to provide for a reinforcing structure in a spinal implant with predictable results.

Using the design of Kalas et al, a triangular portion could be considered a "core" of cancellous bone with the cortical "v" (*for example defined by 22a and 22b of Kalas et al*) portion partially surrounding it.

It would have additionally been obvious to one having ordinary skill in the art at the time of invention to determine a cancellous bone volume of at least 60%, 80%, 95% and/or 98% since it has been held that where the general conditions of a claim are disclosed (*in this case, strength required to support the lumbar spine and using the same source of dense cancellous bone from the calcaneus*) in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733